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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,099	09/17/2003	Jennifer Maw	PD-267.00 (M190.151.101)	3704

63496 7590 04/10/2007

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EXAMINER	
NGUYEN, TUAN VAN	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,099	MAW, JENNIFER	
	Examiner	Art Unit	
	Tuan V. Nguyen	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16,17,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16,17,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *January 9, 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment After Non-Final Rejection

1. According to the Amendment After Non-Final Rejection applicants filed on January 25, 2007, applicant cancelled claims 15, 18, and 19 and adds claims 20-21. Now, claims 1-14, 16, 17, and 20-21 are pending in this present application.

Response to Amendment

2. Applicant's arguments filed on January 25, 2007 with respect to claims (currently amended) 1-14, 16, and 17 have been fully considered but they are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 recites new limitation

"wherein the trigger, including the process, is a homogeneous, integrally formed body" is new matter. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Kroll et al. (U.S. 6,592,513).**

8. Referring to claims **1-9, 11, and 12,** Dragan discloses (see Figs. 1 and 5-7; col. 4, lines 20 to col.5, line 53; and col. 6, lines 31-62) a system for delivering or dispensing a variety of different dental materials in dentistry and certain medical surgical procedure and the system may be used for controlling the deposits of

adhesive (see col. 18, lines 38-44), thus the system is capable of deliver or dispense adhesive to an ear, comprising: a body or dental syringe 20; a handle 22, 23 having a terminus; a trigger 29 pivotally connected to handle 22, 23 through a joint at 24, 24A, and 30 which allows the trigger to pivot about the joint when the trigger is squeezed; a reservoir assembly 61, which can be glass (see col. 7, lines 35-37), having a second end 61B and a first end includes thread 27 for attachment of the reservoir to the body 20; a dispensing mechanism operatively connected at one end to the trigger and at the other end to the reservoir; the dispensing mechanism includes plunger rod 34 having teeth 40 engaged with pawl 41 mounted on the trigger 29 (see col. 5, lines 35-40) and plunger tip 66 (see Fig. 5), wherein the outer diameter of plunger tip is approximately equal to the inner diameter of the reservoir (see col. 6, lines 54-60); a catheter or cannula 74 fluidly connected to the second end of the reservoir assembly 61 by threading or screw fitting 71B (see Fig. 6 and col. 7, lines 30-35). Referring to **claim 10**, Dragan discloses (see Fig. 9) the cannula or tip 102, 102A is permanently affixed to the reservoir 100 by molding process (see col. 9, lines 15-25). Dragan discloses the invention substantially as claimed except for the sealant or adhesive is an otologic adhesive.

9. Still Referring to **claims 1-12,** however, Kroll discloses a method for creating a coupling between an implantable device, such as a tranducer, and the structure of the ear, such as an ossicle by using otologic adhesive such as cyanoacrylate or other surgical adhesive because the formation of a bond at the ossicle/adhesive

interface does not inhibit the natural motion of the ossicle (see Abstract; col. 4, lines 7-10; and col. 7, lines 21-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the device of Dragan to dispensing the otologic adhesive for the application that suggested by Kroll.

10. **Claims 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Kroll et al. further in view of Silverman et al. (U.S. 6,575,896).**

11. Referring to claims **13 and 14**, Dragan discloses the invention substantially as claimed except for a specific size of the needle gauge. Silverman discloses an apparatus and method of injecting a nonbiodegradable such as cyanoacrylate, which is a non-toxic chemical inert prepolymer for in situ (see col. 11, line 48-59) through a needle having a gauge size ranging from 16 to 28 preferably ranging from 23 to 26 gauge (see col. 4, lines 15-23) for treating of Gastroesophageal reflux disease. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use needle having gauge size ranging 10 to 26 for delivery of cyanoacrylate, as disclosed by Silverman, to incorporate into the device, as disclosed by Dragan because Applicant has not disclosed that the needle size ranging from 10 to 50 gauge provides an advantage, or solves a stated problem. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use needle having size ranging from 10 to 50 gauge,

since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Referring to **claim 16**, Dragan discloses the invention substantially as claimed except for the material is cyanoacrylate adhesive. Silverman discloses an apparatus and method of injecting a nonbiodegradable such as cyanoacrylate, which is a non-toxic chemical inert prepolymer for in situ (see col. 11, line 48-59) for treating of Gastroesophageal reflux disease. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use cyanoacrylate, as disclosed by Silverman, to incorporate into the device, as disclosed by Dragan to gain the advantage of cyanoacrylate is a non-toxic and chemical inert.

13. **Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Kroll et al. further in view of Wirt et al. (U.S. 6,648,852).**

14. Referring to **claim 17**, the modified device of Dragan discloses the invention substantially as claimed except for the adhesive is a fibrin-base adhesive. However, Wirt discloses that fibrin-base adhesive for bond and or seal tissue is old and well known in the art (see col. 1, lines 28-38). Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use fibrin-base adhesive as disclosed by Wirt et al. because Applicant has not disclosed that the fibrin-base adhesive provides an advantage, or solves a stated problem.

15. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Kroll et al. further in view of Epstein (U.S. 5,226,877).**

16. The modified device of Dragan discloses the invention substantially as claimed except for the ratchet mechanism capable of delivery a dosage as small as 5-10 microliter. However, Epstein discloses that a ratchet mechanism for dispensing fibrinogen adhesive with such accuracy as claimed by the applicant (see col. 14, lines 35-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the ratchet mechanism as disclosed by Searger et al. because this will provide the surgeon ability to dispense a small amount of adhesive as much as one microliter or perhaps up to ten microliters for coupling the transducer to the oscicle as suggested by Kroll.

17. **Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Kroll et al. further in view of Seager et al. (U.S. 4,744,494).**

18. Referring to **claim 21**, the modified device of Dragan discloses the invention substantially as claimed except for the trigger and the process is a homogeneous, integrally formed body. However, Seager discloses such a mechanism. Seager discloses (see Figs. 1, 3 and 5) the trigger 16 and the pawl 22 or process 22 is a homogeneous, integrally formed body (see col. 3, lines 55 to col. 4, line 10). Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to make the trigger and the pawl as a homogeneous, integrally formed body as disclosed by

Seager et al. because Applicant has not disclosed that the design provides an advantage, or solves a stated problem.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
April 3, 2007

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/5/07.